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**REVIEW OF UNCERTAINTY ANALYSIS AND RISK ASSESSMENT FOR
ROCKY FLATS OPERABLE UNIT 1**

March 1994

REVIEW DRAFT

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ADMIN RECORD

SUMMARY

The Rocky Flats Plant (RFP) Environmental Restoration (ER) Program has completed both public (human) health and ecological baseline risk assessments at Operable Unit 1 (OU1). The human health risk assessment included a quantitative uncertainty analysis (QUA) that characterized the combined uncertainty of exposure and toxicity estimates. This document reviews the methods used to conduct that QUA and recommends possible areas of improvement. Additionally, general reviews of the public health and ecological evaluations are provided.

Review of the Quantitative Uncertainty Analysis

The approach recommended by EPA to quantify human health risk is to calculate a single point estimate of "reasonable maximum exposure" (RME) for each current and future receptor of interest (EPA 1989a). Inherent variability and uncertainty in receptor and site parameters make the calculated health risks uncertain. QUA can generate full probability distributions for health risks, providing considerably more information than a single risk estimate for an RME receptor.

The QUA for OU1 does not address the intended use of the analysis. This is an important omission because the analytical precision required for the QUA is contingent on the intended use. To date, QUA results have generally been used to demonstrate that remediation goals derived on the basis of risk estimates for RME receptors are protective (i.e., by showing that the risk estimate for the RME receptor is much higher than the 90% percentile risk level predicted using QUA). The existing QUA for OU1 would be useful for this purpose with only minor revisions. However, if the intended use of the QUA results is to set remediation goals corresponding to the high end of the QUA-predicted risk distribution (e.g., 95% percentile), then a more comprehensive analysis would be needed. It should be noted that, per EPA guidance (EPA 1989a, 1991a), the latter use for QUA (i.e., to set remediation goals) is not recommended. To date, QUA has been most successfully utilized in characterizing the uncertainty of receptor exposure levels. Although toxicity values are highly uncertain, it is currently unlikely that extensive characterization of toxicity value distributions will impact regulatory decisions.

At a statistical level, the objectives of the QUA should also have been defined in order to identify the range of the risk distribution that is of interest. Methods used in QUA to identify the maximum likelihood estimate (MLE) for risk differ substantially from those used to identify the 95% upper confidence level (UCL). It is suggested that the focus of the QUA should be on estimation of the 95% UCL for the risk value rather than the median value, since the 95% UCL most closely approximates current regulatory guidelines. Although various percentiles for the risk distribution were presented in

Table F7-31 of the QUA, the methods used to generate the risk distribution were probably not sensitive enough to estimate the 95% UCL with a high degree of confidence

Following is a summary of potential revisions to the QUA which could be readily incorporated and significantly improve the quality of the assessment

- *The most significant improvement in the QUA could be achieved by presenting the risk distribution based on uncertainty analysis of exposure separately from the risk distribution incorporating toxicity uncertainty (i.e., separate from the results which include cancer potency factor distributions)* This would yield valuable information on the proportion of uncertainty contributed by both the exposure analysis and the toxicity analysis, and would address regulatory concerns over incorporating distributions for cancer potency factor values in the QUA
- The parameter distributions should be re-examined and literature searches conducted to ascertain that the best available data are incorporated in the QUA. Additionally, the literature search should be used to identify appropriate correlation coefficients (if available) for incorporation in the existing analysis
- The 95% UCL of the cancer potency factor distributions used in the QUA for OU1 should be clearly identified to facilitate easy comparison with EPA-generated values

Other revisions could require substantial additional analysis and should be justified by further identification of the intended utilization of the QUA. These include 1) an investigation of the separate effects of uncertain and variable parameters to obtain an estimate of the uncertainty associated with the 95% UCL for human health risk, 2) possible supplements to the ORNL method used to generate cancer potency factors that would address more sources of uncertainty, 3) incorporation of Monte Carlo methods which address correlated parameters for which correlation coefficients are unavailable, and 4) assessment of non-cancer risk uncertainties

Review of the Public Health Evaluation

The PHE for OU1 was generally well conducted and thorough. Methods utilized followed current EPA guidance with the exception of the omission of radiological dose calculations.

Although several recommendations for the improvement of the PHE are suggested in the text, the following are considered the most consequential:

- Radiological doses should be presented

- In addition to presented risks, the risks to all receptors should be presented assuming that the hot spots of plutonium-239, plutonium-240, and americium-241 have been removed
- The population risks presented should be verified by using standard methods for radiation risk assessment

Review of the Ecological Evaluation

Recommendations for strengthening the EE which could be readily incorporated with the existing data and only limited additional analyses include

- A complete reorganization of the document format to more closely follow the format sequence of the EPA ecological risk assessment framework and other EPA guidance (EPA 1989b)
- Clear identification of the hypotheses of the risk assessment.
- Addition of a qualitative discussion of possible synergistic and cumulative effects of contaminants
- Addition of a qualitative discussion of the potential for contaminants from other source areas impacting OU1
- Revision to provide additional details for the field survey and sampling methods and for the various biometrics used as endpoints
- If the selected reference site is retained, provision of a discussion regarding possible contamination of the reference area from past activities and current transport pathways from the RFP, and the consequences to the value of the biotic comparisons made in the EE
- Provision of estimates of the areal sizes of the various vegetation community/habitat types, and also a discussion on the possible effects of different habitat sizes and habitat patchiness between OU1 and the current reference site on species diversity and richness, composition, and abundance
- Revision of the conceptual model to include multiple sources
- Provision a summary of the fate and transport modeling and analyses conducted in other portions of the RFI/RI for OU1
- Addition of definitions for assessment endpoint, measurement endpoint, and receptor should be provided Each endpoint used should be identified as either an assessment or measurement endpoint
- Revision of the conceptual model to include each of the IHSS's and the five contaminated media as sources
- Revision to consider biota as receptors rather than as sources or release mechanisms Food chain pathways including these and other receptors should be developed and shown

- Revision of the presentation of the methods used to develop the TRV's, MATC's, and ecological effects criteria, as well as the procedures and rationale used for exposure estimation
- Addition of sensitivity analyses for equation parameters

Recommendations that would require additional field and laboratory activities and data analyses include

- Evaluation of additional receptors, particularly from among the song birds, herpetofauna, and larger small mammals. Additional biotic surveys, tissue analyses, development of new food chain pathways, uptake modeling, and exposure evaluations would then be needed
- Performance of toxicity tests using contaminated and uncontaminated media from each of the IHSS's and the different habitat areas
- Identification of future risks. If contaminant fate and transport modeling is currently available, it may be possible to address future risks with available data, at least to the receptors identified in the EE